

2016

Brand Name Drug Manufacturers Will Make Them an Offer They Can Refuse: Reverse Payment Settlements and Actavis

Jillian Freda

Follow this and additional works at: https://scholarship.shu.edu/student_scholarship



Part of the [Law Commons](#)

Recommended Citation

Freda, Jillian, "Brand Name Drug Manufacturers Will Make Them an Offer They Can Refuse: Reverse Payment Settlements and Actavis" (2016). *Law School Student Scholarship*. 735.
https://scholarship.shu.edu/student_scholarship/735

Brand Name Drug Manufacturers Will Make Them an Offer They Can't Refuse: Reverse Payment Settlements and *Actavis*

Jillian Freda

TABLE OF CONTENTS

- I. Introduction
- II. Generic and Brand Name Drugs
- III. Reverse Payment Settlements and *Actavis*
- IV. The Split Over the *Actavis* Decision
- V. No-Authorized-Generic Provisions
- VI. Analysis: Future Courts Should Review Non-Cash Reverse Payment Settlements Under the Rule of Reason Test
- VII. Conclusion

I. Introduction

Health care spending in the United States is extremely high; “the spending grew 3.7 percent in 2012 to \$2.8 trillion, or \$8,915 per person.”¹ “In 2012, prescription drug spending [was] estimated to have accounted for \$260.8 billion of national health spending...For 2015 through 2022, rising drug prices and expected aggregate utilization [accelerate] overall projected average annual growth in prescription drug spending (6.5 percent per year).”²

The prescription drugs spending might be due to the variance in the categorization of drugs. These categories are commonly known as brand name drugs and the generic drugs. A brand name drug is “a medication sold by a pharmaceutical company under a trademark-protected name. Brand name medications can only be produced and sold by the company that holds the patent for the drug. Brand name drugs may be available by

¹ ACA International- Healthcare Collection Statistics-facts and statistics about healthcare debt and collections. <http://www.acainternational.org/products-healthcare-collection-statistics-5434.aspx>

² National Health Expenditures Projections 2012-2022 Forecast Summary. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/proj2012.pdf>

prescription or over the counter.”³ Despite these patent holdings, brand name drugs fight for the market with generic drugs. A generic drug is “a drug product that is comparable to a brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics and intended use.”⁴ Because generic drugs are so “comparable,” brand name drug manufacturers attempt to keep generics out of the market for as long as possible.⁵ Reverse payment settlements are an example of such a means to prohibit or exclude generic drugs from the market. Reverse payment settlements are “payments from pharmaceutical patent holders to generic manufacturers in return for settling challenges to the patent’s validity, and for delaying the introduction of generics into the market.”⁶ These settlement are concerning because they allow the brand drug manufacturer, the patent holder, to evade competition by furnishing some of the monopoly profits to the generic entrant and although this is beneficial to the brand and the generic drug manufacturers, the cost of this settlement is thrust upon the consumers and their health care costs.⁷

The Supreme Court in *Actavis* held that courts should use the rule of reason when analyzing an antitrust claim such as a reverse payment settlement.⁸ The Court laid out five factors for courts to consider when they are structuring the rule of reason in antitrust litigation.⁹ However, the lower courts are free to examine other factors and

³ About Health, Brand Name Drugs,
http://drugs.about.com/od/bdrugandmedicalterms/g/brandname_def.htm

⁴ FDA, Generic Drugs, Pg. 7
<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm127615.pdf>

⁵ *Id.*

⁶ Am. Bar Ass’n, “Pay-for-Delay” Settlements: Antitrust Violation or Proper Use of Pharmaceutical Patent Rights? (2011), available at http://www.americanbar.org/publications/blt/2011/01/02_hanks.html

⁷ *Id.*

⁸ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236.

⁹ *Actavis*, 2234.

considerations outside of this list as well.¹⁰ The Court held that “large and unjustified” cash reverse payment settlements are subject to the rule of reason, but there are multiple ways to structure an agreement that will ultimately generate a substantial profit to the generic drug manufacturer without the generic drug manufacturer physically receiving a cash reverse payment settlement.¹¹ Currently there is a contention over whether the Supreme Court intended only cash reverse payment settlements to be subject to antitrust scrutiny under the rule of reason.¹² Since the *Actavis* holding, four district courts have reviewed the issue of cash reverse payment settlements. Two of these district courts have interpreted *Actavis* to require cash payments.¹³ The other two have acknowledged that “reverse settlements deemed anti-competitive pursuant to *Actavis* can take forms other than cash payments.”¹⁴

This comment attempts to discern the implications of reverse payment settlements on the drug market after the *Actavis* decision. Ultimately, this comment argues that the Supreme Court did not intend to limit antitrust scrutiny to just cash reverse payment settlements. The basis of this position revolves around the intrinsic harm these non-cash settlements have on the market and their tendency to prevent the realization of cheaper drug prices relevant to consumers. Part II of this comment will discuss the relationship between brand name drugs and generic drugs. Part III of this comment will outline

¹⁰ Id. at 2231.

¹¹ Id. at 2237.

¹² In re Lamitcal Direct Purchaser Antitrust Litigation, No. 12-cv-995, 2014 WL 282755 at *7 (D.N.J. Jan. 24, 2014); In re Loestrin 24 Fe Antitrust Litigation, MDL No. 13-2472-S-PAS, 2014 WL 4368924, at *13 (D.R.I. Sept. 4, 2014). In re Niaspan Antitrust Litigation, 2014 WL 4403848, at *10 (E.D. Pa. Sept. 5, 2014); In re Nexium (Esomeprazole) Antitrust Litigation, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

¹³ In re Lamitcal Direct Purchaser Antitrust Litigation, No. 12-cv-995, 2014 WL 282755 at *7 (D.N.J. Jan. 24, 2014); In re Loestrin 24 Fe Antitrust Litigation, MDL No. 13-2472-S-PAS, 2014 WL 4368924, at *13 (D.R.I. Sept. 4, 2014).

¹⁴ In re Niaspan Antitrust Litigation, 2014 WL 4403848, at *10 (E.D. Pa. Sept. 5, 2014); In re Nexium (Esomeprazole) Antitrust Litigation, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

reverse payment settlements and the *Actavis* decision. Part IV of this comment will evaluate the split among the courts after the *Actavis* decision, about whether the Supreme Court intended to subject non-cash reverse payment settlements to the rule of reason analysis. Part V will argue that no-authorized-generic provisions negatively impact the market essentially as much as cash reverse payment settlements do. Part VI will analyze the antitrust implications of limiting the rule of reason analysis to solely cash reverse payments, and thus why non-cash reverse payments settlements should be subject to equal scrutiny. Finally, Part VII will conclude by reinforcing the position that the *Actavis* decision should not be limited to cash reverse payment settlements.

II. Generic and Brand Name Drugs

The brand name drug approval process is both expensive and time consuming. The process is lengthy, consisting of the drug manufacturer's pre-clinical stage, their clinical stage, and the FDA's review.¹⁵ First, the drug manufacturer seeks advice from the FDA, and then submits an Investigational New Drug Application (IND).¹⁶ Sponsors, or the companies and organizations that develop the drug, "must show that the FDA results of preclinical testing in a laboratory animals and what they propose to do for human testing," and then the FDA determines whether to permit human testing.¹⁷ The clinical trials with humans cannot commence until the FDA and a local institutional review board (IRB), "a panel of scientists and non-scientists in hospitals and research institutions that oversee clinical research, review the company's IND."¹⁸ The IRBs

¹⁵ The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, (March 3, 2015 at 8:05am), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm>

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

approve the clinical trial, its protocols, procedure, participants, objectives, etc.¹⁹ The IRBs primary purpose is to “make sure the study is acceptable, that participants have given consent and are fully informed of their risks, and that researchers take appropriate steps to protect patients from harm.”²⁰ Phase 1 of the clinical trial testing is completed with health volunteers.²¹ The Phase 1 “goal is to determine what the drug’s most frequent side effects are, and often, how the drug is metabolized and excreted.”²² Pursuant to the absence of any formally recognized prohibited measurements of toxicity, thresholds Phase 2 commences.²³ Phase 2 “aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition.”²⁴ The patients receiving the drug are compared to patients receiving a placebo or different drug, the sponsors evaluate the side effects.²⁵ Phase 1 and Phase 2 studies are much smaller than a Phase 3 study.²⁶ Phase 3 studies “gather more information about safety and effectiveness, studying different populations and different dosages and using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people.”²⁷ These clinical trials typically take a few years.²⁸

A New Drug Application (NDA) is the formal application of request for the FDA’s approval in regards to marketing in the United States; an NDA “includes all animal and human data and analyses of the data, as well as information about how the

¹⁹Id.

²⁰ Id.

²¹ Id.

²² Id.

²³Id.

²⁴ Id.

²⁵ Id.

²⁶Id.

²⁷ Id.

²⁸ Id.

drug behaves in the body and how it is manufactured.”²⁹ After the NDA is submitted, the FDA has sixty days to file it for review, and “in accordance with the Prescription Drug User Free Act (PDUFA), the FDA’s Center for Drug Evaluation and Research (CDER) expects to review and act on at least 90 percent of NDA’s for standard drugs no later than 10 months after the applications are received.”³⁰ Even after all three phases of clinical trials, “postmarket requirement and commitment studies are required of or agreed to by a sponsor and are conducted after the FDA has approved a product for marketing.”³¹ These studies are used to “gather additional information about a product’s safety, efficacy, or optimal use.”³²

Clearly, the FDA drug approval process is a complex and financially onerous process; not all drug manufacturers have the resources and money to fund such an undertaking. The brand name drug manufacturer performs the drug approval process, which allows a generic drug manufacturer to escape the hassle, but the generic drug must necessarily be extremely similar to the brand name drug. The FDA requires that generic drugs “to have the same quality, strength, purity, stability as their brand name versions.”³³ Generic drugs are thoroughly tested to make sure that their performance and ingredients meet the FDA’s standards of equivalency.”³⁴ Therefore the only true difference between a generic drug and a brand name drug is not one of composition, but rather the legal holding of a patent.³⁵ A patent “for an invention is a grant of the property

²⁹ Id.

³⁰ Id.

³¹ Id.

³² Id.

³³ 21 U.S.C. § 355, see Health Smart.

<http://www.healthsmart.com/WellnessResourceCenter/GenericVsBrandDrugs.aspx>

³⁴ Id.

³⁵ Id.

right to the inventor, issued by the United States Patent and Trademark Office.”³⁶ The patent grant gives the inventor “the right to exclude others from making, using, offering for sale...in...or importing the invention to the United States”³⁷ Typically, when a company develops a new drug, they submit it for FDA approval, and a 20-year patent is issued.³⁸ The 20-year patent prevents other companies from selling the new drug “during the life of the patent,” but as expiration approaches “any drug manufacturer can apply to the FDA to sell its generic version.”³⁹ This application process is completed in accordance with the provisions specified under the Hatch-Waxman Act.⁴⁰

The Hatch-Waxman Act promotes competition by helping a generic brand reach the market faster.⁴¹ As previously noted, establishing a new prescription drug into the market is both expensive and time consuming for drug manufacturers.⁴² Thus, the Hatch-Waxman Act allows a generic manufacturer to “obtain marketing approval through abbreviated procedures.”⁴³ The generic manufacturer files an Abbreviated New Drug Application “specifying that the generic has the ‘same active ingredients as,’ and is ‘biologically equivalent’ to, the already-approved brand-name drug.”⁴⁴ This “piggy-backing” allows the generic drug manufacturers’ to benefit from the brand-name drug manufacturers’ time and money spent in getting their own FDA approval, because they

³⁶ 21 USCS prec § 1, see United States Patent and Trademark Office, General Information Concerning Patents- What is a Patent?, <http://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-2>

³⁷ United States Patent and Trademark Office, General Information Concerning Patents- What is a Patent?

³⁸ Health Smart.

³⁹ Id.

⁴⁰ 98 P.L. 417, 98 Stat.1585.

⁴¹ Id., see Actavis, at 2237.

⁴² Id. at 2228.

⁴³ Id.

⁴⁴ Id., citing Caraco Pharm, Labs., Ltd. v. Novo Nordisk A/S 566 U.S., 132 S. Ct. 1670 1676, 182 L. Ed. 2d. 678, 687 (2012).

do not need to physically create the drug and obtain the original marketing approval.⁴⁵ Essentially, this Act is an empirical exercise in the process of expediency through the mitigation of redundancy. The Hatch-Waxman Act provides an “incentive” to be the first to file an Abbreviated New Drug Application under paragraph IV.⁴⁶ This applicant will “enjoy” a period of 180 days of exclusivity with the brand name drug manufacturer; in this period they will obtain duopoly profits.⁴⁷ Duopoly is “a situation in which two companies own all or nearly all of the market for a given product or service.”⁴⁸ At the conclusion of this period, the brand name drug manufacturer and the generic manufacturer that filed first, will then “obtain only the lower profits associated with the free market.”⁴⁹

There is clear tension between the brand name drug and generic drug because they are direct competitors. These Abbreviated New Drug Applications are challenges to the brand name drug manufacturer’s patent. Because “the costs of research, development, and obtaining FDA approval are so substantial, it takes a long time for a pharmaceutical manufacturer to recover its investment in a new product and begin to make a profit.”⁵⁰ The brand name drug manufacturer put a tremendous amount of time and money into the clinical trials and approval process, therefore they want to recoup that initial investment and make a profit. As such, the Abbreviated New Drug Application

⁴⁵ Id.

⁴⁶ Id. at 2228-2229.

⁴⁷ Id.

⁴⁸ Definition of duopoly, (Feb. 13, 2015 at 4:06pm), <http://www.investopedia.com/terms/d/duopoly.asp>.

⁴⁹ Fed.Trade Comm’n, Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers, *available at* http://www.ftc.gov/system/files/documents/public_statements/591131/141010actavisspeech.pdf

⁵⁰ Symposium: Tort Reform and American Society: A Dialogue: December 15, 1995: Article: Rationalizing The Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform, 48 Rutgers L. Rev. 883, 931-932.

challenges are huge threats to the brand name drug manufacturer's revenue.⁵¹ Brand name drug manufacturers have patents to protect their blockbuster drugs. A blockbuster drug is an extremely popular drug that generates annual sales of at least \$1 billion for the company that creates it.⁵² A blockbuster drug can be the reason for the pharmaceutical company's success, so those companies want to protect the drug; for example assuring the market is exclusive for the drug.⁵³ If the market is free then the blockbuster drug will not be as profitable; this could be devastating to the pharmaceutical company. When "there is a single generic competitor, the generic tends to be priced approximately 25% lower than the brand name counterpart," but when "there are multiple generic alternatives, the price of the generics typically falls to 50% to 80% below the brand name product."⁵⁴ Additionally, "generally within a year of generic market entry, generics will capture 90% of sales and prices will fall as much as 85%."⁵⁵ This data depicts the significance of market control relative to this industry; as well as, the potential destructive force a patent challenge can be for a brand name pharmaceutical manufacturer. Since the brand name drug manufacturer makes substantially more revenue with the generic drug out of the market, the manufacturers are motivated to isolate the market by shutting down the generic competition by splitting their monopoly profits.⁵⁶ They do this by agreeing to the Hatch-Waxman Abbreviated New Drug

⁵¹ In re Loestrin 24, 2014 U.S. Dist. LEXIS at *10, citing DP Compl. ¶ 62, ECF No. 39.

⁵² Definition of blockbuster drug, (Feb. 11, 2015 at 2:38pm), <http://www.investopedia.com/terms/b/blockbuster-drug.asp>.

⁵³ Id.; In re Loestrin 24, 2014 U.S. Dist. LEXIS at *10, citing DP Compl. ¶ 62, ECF No. 39.

⁵⁴ In re Loestrin 24, 2014 U.S. Dist. LEXIS at *10, citing DP Compl. ¶ 62, ECF No. 39.

⁵⁵ Id. at *10-11

⁵⁶ Payment after Actavis, 29.

Application as opposed to litigation where they could lose their drug monopoly completely.⁵⁷

III. Reverse Payment Settlements and *Actavis*

Reverse payment settlements involve both patent law and antitrust law, *E.g. Actavis*.⁵⁸ Reverse payment settlements involve patent law but they are “unusual” because “where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle a lawsuit.”⁵⁹ It is called a reverse payment settlement because it “requires the patentee to pay the alleged infringer, rather than the other way around.”⁶⁰ The patent holder, through the payment, is almost re-purchasing the exclusive right to sell their drug because they would risk losing this right if their patent were held invalid or not infringed in patent litigation.⁶¹ Since a patent license “grants its owner wide latitude in protecting his monopoly entitlement, courts have developed antitrust law to reduce the negative effects of the use of the monopoly power.”⁶² The valid patent “excludes all except its owner” from the right of the protected product, or in this case, drug.⁶³ Since the patent owner has exclusive rights to the product, they can charge high prices for that product.⁶⁴ An invalidated patent cannot exclude, “and even a valid patent confers no right to exclude products or

⁵⁷ Hatch-Waxman Use or Abuse. Pg. 327-328

<http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1354&context=btlj>

⁵⁸ *Actavis*, 2227.

⁵⁹ *Id.* at 2235, citing 1 H. Hovenkamp, M. Janis, M. Lemley, & C. Leslie, *IP and Antitrust* § 15.3, p. 15-45, n. 161 (2d ed. Supp. 2011).

⁶⁰ *Actavis*, 2227.

⁶¹ *Id.* at 2234.

⁶² Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 *N.Y.U. L. Rev.* 1553, 1558 (2006).

⁶³ *Actavis*, 2231, citing *United States v. Line Material Co.*, 333 U.S. 287, 308, 68 S. Ct. 550, 92 L.Ed. 701 (1948).

⁶⁴ *Id.* at 2231.

processes that do not actually infringe.”⁶⁵ The Sherman Act regulates the activities in which the patent owners can engage and additionally, enforces strict limitations on these patent owners.⁶⁶

Congress passed antitrust laws like the Sherman Act to preserve “free and unfettered competition as the rule of trade.”⁶⁷ The Sherman Act “outlaws ‘every contract, combination, or conspiracy in restraint of trade’ and any ‘monopolization, attempted monopolization, or conspiracy or combination to monopolize.’”⁶⁸ The rule of reason “is the judicial doctrine [,] which [states] that a trade practice violates the Sherman Act only if the practice is an unreasonable restraint of trade, based on economic factors.”⁶⁹ In addition, the Federal Trade Commission Act “bans ‘unfair methods of competition’ and ‘unfair or deceptive acts or practices.’”⁷⁰ Reverse payment settlements can undermine the goal of a “free and unfettered competition” because the brand name drug using their monopoly power and the resources that have been acquired through that exercise of monopoly power.

Reverse payment settlements involve antitrust law. For these settlements, “the antitrust issue arises when two competing drug makers settle a patent suit before trial with a substantial cash payment from the patent holder to the generic manufacturer.”⁷¹ This transaction denies consumers the benefit of lower prices because they eliminate

⁶⁵ Id.

⁶⁶ Id. at 2232, citing *U.S. v. Singer Mfg. Co.*, 197 U.S. 174, 83 S. Ct. 1773, 10 L. Ed. 2d 823.

⁶⁷ Fed. Trade Comm’n, *The Antitrust Laws* (2014), available at <http://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws>

⁶⁸ Id.

⁶⁹ Rule of Reason Law & Legal Definition. USLEGAL.com., <http://definitions.uslegal.com/r/rule-of-reason/>

⁷⁰ Fed Trade Comm’n. *The Antitrust Laws* (2014), available at <http://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws>

⁷¹ Hemphill, 1557.

competition in the drug market.⁷² It is “large cash payment from the patent owner to the manufacturer, not the litigation settlement in and of itself, that renders the transaction anticompetitive,” and therefore, these payments and other forms of consideration must be examined under the rule of reason.⁷³

The Supreme Court in *Actavis* held that reverse payment settlements would be analyzed through the rule of reason.⁷⁴ The Supreme Court focused on the size of the payment, stating, “by examining the size of the [large and unjustified] payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent.”⁷⁵ The Court therefore rejects the Eleventh Circuit’s decision to “provide near-automatic antitrust immunity to reverse payment settlements” within their scope of patent test.⁷⁶ The scope of patent test is a per se rule under the scope of the patent, meaning that any agreement to settle a patent infringement eludes antitrust laws, if two criteria are met: 1.) There was no fraud when the brand name drug acquired the patent, and 2.) The settlement does not delay entry into the marketplace beyond the scope of the patent.⁷⁷ Additionally the Court rejects the Third Circuit’s “quick-look” approach, which holds that “reverse payment settlement agreements are presumptively unlawful” and as “prima facie evidence of an unreasonable restraint of trade,” shifting the burden to the case’s defendant “to show empirical evidence of precompetitive effects.”⁷⁸ After rejecting both the scope of patent test and

⁷² Id.

⁷³ Id.

⁷⁴ *Actavis*, 2237.

⁷⁵ Id.

⁷⁶ Id.

⁷⁷ *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

⁷⁸ Id. See *California Dental*, 526 U.S., at 775.

the quick look test, the Court determined the rule of reason to be applicable.⁷⁹ The rule of reason test in its antitrust review does not involve an assessment of patent validity.⁸⁰

The Supreme Court laid out five factors, when a court is analyzing an antitrust claim, within the rule of reason, when the court is analyzing an antitrust claim.⁸¹ First, the court must determine if “the specific restraint at issue has the “potential for genuine adverse effects on competition.”⁸² Second, “[the] anticompetitive consequences will at least sometimes be prove[n] unjustified.”⁸³ “The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement.”⁸⁴ Third, “where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice.”⁸⁵ “At least the ‘size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power’- namely the power to charge prices higher than the competitive level.”⁸⁶ Fourth, “an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed” because “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”⁸⁷ Fifth, the court needs to look at the factors driving the “large, unjustified reverse payment.”⁸⁸ The court needs to ask the relevant antitrust question:

⁷⁹ Actavis, 2237.

⁸⁰ Id.

⁸¹ Id. at 2234.

⁸² Id., citing *Indiana Federation of Dentists*, 476 U.S., at 460-461, 106 S. Ct. 2009, 90 L. Ed 2d 445.

⁸³ Id. at 2235-2236, citing *California Dental Ass’n v. FTC*, 526 U.S. 756, 786-787, 119 S. Ct. 1604, 143 L. Ed. 2d 935 (1999).

⁸⁴ Id. at 2236.

⁸⁵ Id., citing 7 *Areeda* ¶1503, at 392-393.

⁸⁶ Id., citing 12 *Areeda* ¶2046, at 351.

⁸⁷ Id. at 2236-2237, citing 12 *Areeda* ¶2046, at 350-352.

⁸⁸ Id. at 2237.

“What are those reasons? If the basic conclusion resembles a desire to maintain and to share patent-generated monopoly profits, then in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.”⁸⁹

The *Actavis* Court states that the lower courts can apply the rule of reason in an antitrust litigation on a case-by-case scope of evaluation.⁹⁰ The Court established a number of factors, including: payment size, the “redeeming virtues” of the agreement, market power, and the adverse effects on competition, to examine when determining whether a reverse payment is anticompetitive.⁹¹ However, the lower courts are free to examine other factors and considerations outside of this list as well.⁹² The Court held that “large and unjustified” cash reverse payment settlements to the rule of reason, but there are multiple ways to circumvent the split of the interpretive law through structuring an agreement that will ultimately generate a substantial profit to the generic drug manufacturer without the generic drug manufacturer physically receiving a cash reverse payment settlement. Since the lower courts are open to case specific evaluations using the rule of reason, the test should be applied to non-cash settlements as well. Non-cash settlements can too exceed a consideration not available as a direct consequence of winning the lawsuit.⁹³

IV. The Split Over the *Actavis* Decision

Four district courts have tackled the issue of whether the *Actavis* Court intended the decision to apply exclusively to cash reverse payment settlements or whether non-

⁸⁹ Id.

⁹⁰ Id. at 2238.

⁹¹ Id. at 2231; Remarks of Joshua D. Wright, Commissioner of Federal Trade Commission, *FTC v. Actavis and the Future of Reverse Payment Cases*, 6.

⁹² Id.

⁹³ *Payment after Actavis*, 26.

cash settlements must also be analyzed under the rule of reason. Two of the district courts found that *Actavis* requires the payment to be cash in order to be subject to the rule of reason analysis.⁹⁴ The other two have held “reverse settlements deemed anti-competitive pursuant to *Actavis* can take forms other than cash payments.”⁹⁵ The split is integral because, depending on which court the parties are in, manufacturers can evade the antitrust scrutiny and this was most likely not the Court’s objective.

The court in *Lamitcal Direct* summarized the *Actavis* holding and found that it contained a three-part test: “two steps to determine when to apply this rule of reason, followed by an application of the rule of reason to the scenario.”⁹⁶ In step one, “a district court must ask, is there a reverse payment?...[T]he answer hinges on what the parties exchanged in the settlement and must include money.”⁹⁷ In step two, “a district court must ask, is that reverse payment large and unjustified?”⁹⁸ Because the Supreme Court expressed that “only certain reverse payments will actually warrant scrutiny.”⁹⁹ Finally, step three is the rule of reason and the five factors in *Actavis*.¹⁰⁰ The *Lamitcal Direct* court described the *Actavis* factors as:

First, Does the payment have the ‘potential for genuine adverse effects on competition’? Second, Is the payment justified in some way, perhaps because it approximates ‘litigation expenses saved through the settlement’ or compensates

⁹⁴ In *re Lamitcal Direct Purchaser Antitrust Litigation*, No. 12-cv-995, 2014 WL 282755 at *7 (D.N.J. Jan. 24, 2014); In *re Loestrin 24 Fe Antitrust Litigation*, MDL No. 13-2472-S-PAS, 2014 WL 4368924, at *13 (D.R.I. Sept. 4, 2014).

⁹⁵ In *re Niaspan Antitrust Litigation*, 2014 WL 4403848, at *10 (E.D. Pa. Sept. 5, 2014); In *re Nexium (Esomeprazole) Antitrust Litigation*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

⁹⁶ *Lamitcal Direct Purchaser Antitrust Litig. v. All Direct Purchaser Action*, 2014 U.S. Dist. LEXIS 9257, *13.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.* at *14. See *Actavis* at 2237 (explaining that “likelihood of a reverse payment bringing about anticompetitive effects” is not presumed but “depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification”).

¹⁰⁰ *Lamitcal Direct*, *14.

the patent challenger for ‘other services...such as distributing the patented item or helping to develop a market for that item’? Third, Does the brand name manufacturer have the market power needed to bring about anticompetitive harm? Fourth, Does the size of the settlement suggest that it is intended to maintain supracompetitive prices and serve as a ‘workable surrogate for a patent’s weakness’? Fifth, Could the parties have settled in some way that did not involve the use of reverse payments?¹⁰¹

The *Lamtical Direct* court asserted that *Actavis* only applies to cash payments because the Supreme Court did use those factors to evaluate a cash payment in that specific case.¹⁰² The *Lamtical Direct* court interpreted Justice Breyer’s statement in *Actavis*, that “in reverse payment settlements...a party with no claim for damages...walks away with money simply so it will stay away from the patentee’s market” to mean that the Supreme Court “considered a reverse payment to involve an exchange of money.”¹⁰³ But the *Lamtical Direct* court also acknowledged Chief Justice Robert’s argument, stating:

[the Justice’s] logic ‘cannot possibly be limited to reverse payment agreements, or those that are large’ suggesting that it must also sweep in ‘other consideration and alternative arrangements’ as well as even ‘the Court’s own solution of negotiated early entry’ and Chief Justice Roberts says that the distinction between money and other transfers of value ‘a distinction without a difference.’¹⁰⁴

Also in *Lamtical Direct*, the court reiterated the Supreme Court’s intention to give patent litigants “latitude to settle without triggering the antitrust scrutiny that large, unjustified reverse payments bring.”¹⁰⁵

Although *Lamtical Direct* agreed with the *Actavis* decision to restrain antitrust scrutiny and to focus on cash reverse payments, other courts have been disagreeing with *Actavis*.¹⁰⁶ In *re Lipitor*, Judge Sheridan stated, “nothing in *Actavis* strictly requires that

¹⁰¹ *Lamtical Direct*, *14-15, see *Actavis* at 2234-2237.

¹⁰² *Lamtical Direct*, *14

¹⁰³ *Lamtical Direct*, *21-22, citing *Actavis*, 2233.

¹⁰⁴ *Lamtical Direct*, *23-24, citing *Actavis*, 2243, 2245.

¹⁰⁵ *Lamtical Direct*, *30.

¹⁰⁶ In *re Lipitor*, In *re Nexim*, *Loestrin*.

the payment be in the form of money.”¹⁰⁷ Similarly, *In re Nexium*, “the court read *Actavis* to sweep in non-monetary payments-‘(n)owhere in *Actavis* did the Supreme Court explicitly require[d] some sort of monetary transaction.’”¹⁰⁸ Here, the court examined settlements involving delayed generic entry and stated,

There is evidence that agreeing to delay market entry is contrary to a generic competitor’s interests, because of the potentially lucrative market for generic Nexium and the risk that by the time the generic competitor enters, the brand manufacturer will have transferred its monopoly power to a slightly reformulated product, shrinking the market for generic Nexium.¹⁰⁹

The brand drug manufacturer is able to use its monopoly power by providing an incentive to the generic drug manufacturer to delay its drug’s market entry date. The brand drug manufacturer can use other agreements in lieu of a lump sum of cash to persuade the generic drug; for example, allowing the generic to join the market without the threat of the brand drug’s generic taking away consumers in a no-authorized-generic provision.¹¹⁰

The *Nexium* court held in denying the Defendant’s motion to dismiss, “unlawful reverse payments are not limited to monetary payments,” and stated, “this [c]ourt does not see fit to read into the [*Actavis*] opinion a strict limitation of its principles to monetary-based arrangements alone.”¹¹¹ Payments, subject to the rule of reason, should include non-monetary based arrangements as well to “align the law with modern-day realities.”¹¹² The court in *Loestrin* expressed that “if courts apply the literal holding *Actavis*, non-cash pay for delay arrangements are likely to evade Sherman Act scrutiny so

¹⁰⁷ *In re Lipitor Antitrust Litig.*, 2013 U.S. Dist. LEXIS 126468 at *95.

¹⁰⁸ *In re Nexium Esomeprozale Antitrust Litig.*, 2013 U.S. Dist. LEXIS 126468 at *15.

¹⁰⁹ *In re Nexium Esomeprozale Antitrust Litig.*, 2014 U.S. Dist. LEXIS 126954 at *57-58.

¹¹⁰ *Id.*

¹¹¹ *Nexium*, *75-76.

¹¹² *Id.*

long as pharmaceutical companies take the obvious cue to structure their settlements in ways that avoid cash payments.”¹¹³ *Loestrin* stated,

When patent holder pays a would-be generic competitor to stay out of the market—regardless of the form of the payment—value is exchanged and the brand manufacturer is able to continue on with fewer competitors. At the very least, ‘there is reason for concern that settlements taking this form tend to have significant adverse effects on competition.’¹¹⁴

The *Actavis* decision found that the rule of reason applies when the plaintiff presents the court with evidence of a cash payment.¹¹⁵ There is tension between the *Actavis* decision and the *Twombly* pleading standards because the *Actavis* decision requires far more specificity than necessary in order to state a proper claim under *Twombly*.¹¹⁶ In *Twombly*, the Supreme Court does “not require heightened fact pleading specifics, but only enough facts to state a claim of relief that is plausible on its face.”¹¹⁷ The Supreme Court held, “stating a claim [under § 1 of the Sherman Act] requires a [plaintiff to file a] complaint with enough factual matter (taken as true) to suggest that an agreement was made.”¹¹⁸ Under § 1 of the Sherman Act, a complaint must allege, “[with] enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement.”¹¹⁹ The *Nexium* court states that under *Twombly*, summary judgment is not appropriate by solely applying cash payments to the *Actavis* rule of reason, because there still could be “sufficient evidence in the record to demonstrate genuine and material factual disputes on the point[.]”¹²⁰ Therefore, reverse payment

¹¹³ *Loestrin*, *37.

¹¹⁴ *Id.* at *39., citing *Actavis*, 2231.

¹¹⁵ *Actavis*, 2236

¹¹⁶ *In Re Loestrin* 24, 2014 U.S. Dist. LEXIS 12332, at *35.

¹¹⁷ *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, at 570.

¹¹⁸ *Id.*, at 556.

¹¹⁹ *Id.*

¹²⁰ *Nexium*, *151

settlements do not specifically need to be “large and unjustified” cash payments to be subjected to antitrust scrutiny, as *Actavis* suggests, but rather a plaintiff just needs to show that enough evidence of sufficient consideration that the brand drug manufacturer possibly violated antitrust laws.¹²¹

V. No-Authorized-Generic Provisions

Under the Hatch-Waxman Act, the 180-day exclusivity period is extremely valuable to the generic that is first to file.¹²² However, the brand name drug manufacturer is permitted to introduce its own generic drug during this exclusivity period.¹²³ The FDA can approve the production of authorized generics by the brand name drug manufacturer; authorized generics are simply their generic version of the brand name drug.¹²⁴ The drug is approved as a brand drug, but marketed as a generic.”¹²⁵ The authorized generic is “sold at a lower cost, and as an alternative, to the branded product.”¹²⁶ Once the life of the patent expires for the brand name drug and generic competition starts, the authorized generic allows the brand name drug manufacturer to “maintain cash flow, albeit at a lower price.”¹²⁷ Authorized generics “decrease the revenues and the profits of a [competing] generic during the exclusivity period. The generic company is thus able to enter the market but will likely not reap the economic and non-tangible benefits of being

¹²¹ *Actavis*, 2237.

¹²² *Actavis*, 2235. (“The special advantage of 180 days of an exclusive right to sell a generic version of the brand-name produce...can be worth several hundred million dollars.”).

¹²³ *Payment After Actavis*, 41, citing *Mylan Pharm Inc. v. FDA*, 454 F. 3d 270, 275-76 (4th Cir. 2006); *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F. 3d 51, 53-55 (D.C. Cir. 2005).

¹²⁴ *Payment After Actavis*, 41-42, citing Fed. Trade Comm’ *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact i* (2011), available at <http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>

¹²⁵ *Id.*

¹²⁶ *Authorized Generics: Antitrust Issues and the Hatch-Waxman Act*, at 1, *available at* https://www.fenwick.com/fenwickdocuments/authorized_generics.pdf.

¹²⁷ *Id.*

a paragraph IV filer.”¹²⁸ Consequently, many “settlements today involve a promise by the brand that it will not launch an authorized generic that would compete with the first-filing generic during the exclusivity period.”¹²⁹ This promise is sometimes referred to as a “no-authorized-generic provision.”¹³⁰ In settlements involving the no-authorized-generic provision, “the generic manufacturer is being compensated for agreeing to delay entry by the brand manufacturer’s own commitment to delay entry with its authorized generic, in effect allowing the generic manufacturer to keep generic prices higher than they would be otherwise.”¹³¹ These clauses are very common and “have involved some of the most popular drugs, including attention-deficit-hyperactivity-disorder (“ADHD”) drug Adderall, antidepressant Effexor, reflux drug Nexium, and clot-preventing Plavix.”¹³² The promise to not introduce an authorized generic during the 180-day exclusivity period is extremely valuable to the first-filing generic. A Federal Trade Commission (FTC) study on authorized generics “concluded that the first-filing generic loses 25% of its market share when it competes with an authorized generic during the exclusivity period...and the first-filer’s revenues are approximately twice as high when it enjoys the period without the authorized generic.”¹³³ The FTC has stated that these agreements may be providing the generic “implicit compensation” for the generic’s

¹²⁸ *Id.* at 5.

¹²⁹ Payment After Actavis, 42.

¹³⁰ *Id.*

¹³¹ Antitrust Analysis of Reverse Payment After Actavis: Three Questions and Proposed Answers, at 16, *available at*

http://www.ftc.gov/system/files/documents/public_statements/591131/141010actavisspeech.pdf

¹³² Payment After Actavis, 42, citing Hemphill, at 684.

¹³³ Payment after Actavis, 41-42, citing Fed. Trade Comm’n Authorized Generic drugs: Short-term and Long-term Impact i (2011), *available at* <http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission> 58-59.

delayed entry.¹³⁴ The agreements are valuable, and although the *Actavis* decision stated cash payments, provisions like the no-authorized-generic provisions exemplify a scenario in which compensation materializes in a form other than a cash payment. The generic drug manufacturer can still receive “implicit compensation.”¹³⁵ The FTC Chairman on the no-authorized-generic Provisions stated:

The clearest and most disturbing finding is that some brand companies may be using the treat of launching an authorized generic as a powerful inducement for generic companies to delay bringing their drugs to market. When companies employ it is a double whammy for consumers. Consumers have to pay higher brand prices while the generic delays its entry and, once generic entry does occur, consumers pay higher prices without the benefit of competition from the authorized generic.¹³⁶

The no-authorized-generic provisions are harming consumers and should not be kept from antitrust scrutiny simply because no cash is passing through hands.

VI. Analysis: Future Courts Should Review Non-Cash Reverse Payment Settlements

Under the Rule of Reason Test

The lower courts should use the rule of reason test when analyzing reverse payment settlements, and this analysis should also include non-cash settlements. The *Actavis* case analyzed monetary reverse payment settlement, but it did not limit the evaluation of reverse payment settlements to just monetary ones.¹³⁷ Courts should use their discretion and the true definition of payment, which is not limited to cash, when subjecting a reverse payment settlement to antitrust scrutiny.¹³⁸ Many forms of

¹³⁴ Federal Trade Commission, Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2010: A Report by the Bureau of Competition, at 1 (May 2011) *available at* <http://www.ftc.gov/os/2011/05/1105mmaagreements.pdf>.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ Lipitor, *26.

¹³⁸ Definition of payment. Webster’s Dictionary, (Feb. 11, 2015 at 2:40pm), <http://www.merriam-webster.com/dictionary/payment>; Definition of payment. Black’s Law Dictionary, (Feb. 11, 2015 at

settlements, for example the no-authorized-generic provision, can violate antitrust law by providing a benefit to the drug manufacturers while harming the competition in the drug industry.

There are four district courts split over whether the *Actavis* decision requires a cash payment to implement antitrust scrutiny.¹³⁹ Two of the district courts hold that the *Actavis* decision only applies to cash payments because the court in *Actavis* evaluated a cash payment.¹⁴⁰ These courts are therefore declaring that besides cash payments, other conduct is a presumption of monopolistic conduct. These courts do not want to subject too much conduct to antitrust scrutiny because they do not want to water down the patent; they want to give the patent litigants “latitude to settle” and thus restrict a court’s input on these business decisions.¹⁴¹ Despite this reasonable conclusion, two district courts hold that the *Actavis* decision does not require a cash payment and therefore does not preclude a non-cash payment from the rule of reason analysis.¹⁴² These courts take the position that nothing in *Actavis* explicitly requires cash, so appropriately the Supreme Court did not intent the decision to require a cash payment for a court to apply the rule of reason.¹⁴³ The *Nexium* court states that courts must “align” the law with modern day practice,

2:41pm), <http://thelawdictionary.org/payment/>. Lipitor, at *60-61, See *Hill v. United States*, 263 F. 2d 885, 886 (3d Cir. 1959); *Staff Builders of Philadelphia, Inc. v. Koschitzki*, 989 F. 2d 692, 695 (3d Cir. 1993) (The common use of the term payment is described as something given to discharge a debt or obligation and does not require the payment to be in the form of money.).

¹³⁹ In re Lamitcal Direct Purchaser Antitrust Litigation, No. 12-cv-995, 2014 WL 282755 at *7 (D.N.J. Jan. 24, 2014); In re Loestrin 24 Fe Antitrust Litigation, MDL No. 13-2472-S-PAS, 2014 WL 4368924, at *13 (D.R.I. Sept. 4, 2014). In re Niaspan Antitrust Litigation, 2014 WL 4403848, at *10 (E.D. Pa. Sept. 5, 2014); In re Nexium (Esomeprazole) Antitrust Litigation, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

¹⁴⁰ In re Lamitcal Direct Purchaser Antitrust Litigation, No. 12-cv-995, 2014 WL 282755 at *7 (D.N.J. Jan. 24, 2014); In re Loestrin 24 Fe Antitrust Litigation, MDL No. 13-2472-S-PAS, 2014 WL 4368924, at *13 (D.R.I. Sept. 4, 2014).

¹⁴¹ Lamitcal Direct, *30.

¹⁴² In re Niaspan Antitrust Litigation, 2014 WL 4403848, at *10 (E.D. Pa. Sept. 5, 2014); In re Nexium (Esomeprazole) Antitrust Litigation, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

¹⁴³ Nexium, *15.

reflecting that the litigants should not elude the rule of reason simply because the payment was not cash; many manufacturers will thus make agreements in non-cash form.¹⁴⁴

The *Lamtical Direct* court is one of the two courts that agreed with the *Actavis* decision.¹⁴⁵ The *Lamtical Direct* court did not want to expand the *Actavis* decision to “trigger” antitrust scrutiny more often.¹⁴⁶ However, courts should trigger the scrutiny when it is justified. Through its inquiry, the *Lamtical Direct* court identified a three-part test in the *Actavis* decision.¹⁴⁷ The first part of the test entails the determination of whether the arrangement a reverse cash payment?¹⁴⁸ But why must the reverse payment settlement include money? When the court in *Lamtical Direct* was evaluating this step, the plaintiffs argued that even though there was no monetary exchange, the generic drug still received “significant consideration, incentive, and benefits.”¹⁴⁹ These terms should be used to formally redefine a reverse payment because none of those terms insinuate that cash is necessary. The definition of significant is something that is “large enough to be noticed or have an effect.”¹⁵⁰ The definition of consideration is a matter weighed into account when formulating an opinion or plan, taken into account, or recompense, payment.”¹⁵¹ The definition of incentive is “something that incites or has a tendency to

¹⁴⁴ Id. at *57-58.

¹⁴⁵ *Lamtical Direct*, *14

¹⁴⁶ Id. at *30

¹⁴⁷ Id. at *13.

¹⁴⁸ Id.

¹⁴⁹ *Lamtical Direct*, *7.

¹⁵⁰ Definition of significant. Webster’s dictionary, (February 12, 2015 at 5:06pm), <http://www.merriam-webster.com/dictionary/significant>.

¹⁵¹ Definition of consideration. Webster’s dictionary, (February 12, 2015 at 5:06pm), <http://www.merriam-webster.com/dictionary/consideration>.

incite to determination or action.”¹⁵² And lastly the definition of benefit is something with a “good or helpful result or effect.”¹⁵³ These definitions depict that items besides cash can incite manufacturers or have an effect on manufacturers’ and their decision-making skills. Thusly items besides cash can justify antitrust scrutiny. Meaning, courts should recognize that consideration is anything that compensates that generic drug manufacturer for allowing the brand drug manufacturer to keep its monopoly and therefore cash payments should not be the only consideration subjected to antitrust scrutiny. The test for the legality of the reverse payment should not rest on the consideration being a cash settlement; rather, “the true test for legality if whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or destroy competition.”¹⁵⁴ A no-authorized-generic provision undoubtedly suppresses competition because the brand name drug manufacturer made an explicit promise to keep their drug off the market. If it’s a restraint on trade and that restraint has anti-competitive consequences, like suppressing competition, then it should be evaluated by the court.

Antitrust scrutiny should not be contingent on whether or not the reverse payment was in the form of cash. The Sherman Act protects competition and a “restraint on trade.”¹⁵⁵ Anything of value could distort the competitive market place and thus it all should be evaluated under the Sherman Act’s rule of reason. As stated in *Lipitor*, “a non-monetary payment includes something of value that can be converted to a concrete,

¹⁵² Definition of incentive. Webster’s dictionary, (February 12, 2015 at 5:06pm), <http://www.merriam-webster.com/dictionary/incentive>.

¹⁵³ Definition of benefit. Webster’s dictionary, (February 12, 2015 at 5:07pm), <http://www.merriam-webster.com/dictionary/benefit>.

¹⁵⁴ Antitrust’s Rule of Reason: Only Competition Matters, 79 Antitrust L.J. 713, 11.

¹⁵⁵ Fed.Trade Comm’n, The Antitrust Laws (2014), available at <http://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws>

tangible or defined amount, which yields a reliable estimate of a monetary payment.”¹⁵⁶ Other forms of settlements, such as the no-authorized-generic provision, also have negative effects on the consumers, but these other forms of antitrust violating settlements just take a little more effort in converting to something more concrete, like how much money the generic drug will make without the brand name drug manufacturer’s generic in the market. Once the court converts the provision to its cash equivalent, then it can proceed to evaluate the non-cash reverse payment from there. The *Lamtical Direct* court addresses whether the settlement is large and unjustified?¹⁵⁷ Money is not the only payment that can be large and unjustified. For example, no-authorized-generic provisions can be equally as large and unjustified. As suggested above, it is something that can be converted to value and this value can be large and unjustified. Although the *Lamtical Direct* court agreed with *Actavis* that the reverse payment settlement should be restricted to monetary payments, the *Lamtical Direct* court still subjected the no-authorized-generic agreement to the five considerations laid out in *Actavis*.¹⁵⁸ Through the evaluation the court determined that the no-authorized-generic agreement was reasonable; it is still significant that the court was able to evaluate this agreement through the considerations depicting that the court believed it was a reverse payment settlement that was large and unjustified.¹⁵⁹ The final step in the *Lamtical Direct* court’s three-step analysis applies the *Actavis*’ five considerations to the agreement.¹⁶⁰

¹⁵⁶ *Lipitor*, *61.

¹⁵⁷ *Lamtical Direct*, *13.

¹⁵⁸ *Lamtical Direct*, *18

¹⁵⁹ *Id.*

¹⁶⁰ *Lamtical Direct*, *14.

The *Actavis* court proposed five considerations when reviewing a reverse payment settlement.¹⁶¹ The first consideration calls for the court to ask whether the payment has the potential for genuine adverse effects on competition?¹⁶² An agreement like the no-authorized-generic provision has adverse effects on competition because it eliminates competition, and allows the generic brand to be the only generic manufacturer in the market, resulting in higher than average generic pricing which is a detriment to the costumers.¹⁶³ The second consideration is whether the reverse payment amounts to more than the generic drug manufacturer, or patent challenger, would receive in the patent litigation.¹⁶⁴ A no-authorized-generic agreement can be more than the generic would receive in a patent litigation. As a method of comparative analysis, the court can convert the agreement to a monetary amount and compare them.

Courts should simply start estimating the monetary value of an agreement, then the courts can rightfully stop differentiating cash reverse payments from non-monetary reverse payments. Judge McHugh in *Nexium* ruled, “settlements [are] only used as a factual basis for the plaintiffs’ antitrust claims.”¹⁶⁵ The court just needs to be satisfied that the payment was consideration or value violating antitrust laws and by allowing a plaintiff to estimate a monetary value the courts should advance to antitrust analysis.

¹⁶¹ *Actavis*, 2234.

¹⁶² *Id.*

¹⁶³ FTC Report Examines How Authorized Generics Affect the Pharmaceutical Market, available at <http://www.ftc.gov/news-events/press-releases/2011/08/ftc-report-examines-how-authorized-generics-affect-pharmaceutical>.

¹⁶⁴ *Actavis*, 2235-2236.

¹⁶⁵ Judge Says *Actavis* Not Limited to Cash Deals, available at <http://www.law360.com/articles/583706/judge-says-actavis-not-limited-to-cash-deals>.

The third consideration is to determine the anticompetitive harm.¹⁶⁶ The no-authorized-generic agreement is categorically anti-competitive because it delays generic market entry and consequently, leaves the market to just the duopoly of the brand drug manufacturer and the generic drug manufacturer.¹⁶⁷ The result is detrimental to consumers as there are no economic forces in play, which may counteract the stabilization of high market prices.¹⁶⁸

The fourth consideration involves an analysis in relation to the size of the reverse payment settlement.¹⁶⁹ As previously noted, the court can convert the no-authorized-generic agreement to a more tangible amount and then examine the size of it. But even without converting the agreement, the agreement (on its face) shows that it is extremely advantageous in terms of profitability and market control/retention reference to brand name drug manufacturers. The brand name drug manufacturer is realizing extremely substantial and significant benefits from it because it does not have to proceed with patent litigation and because it can still charge high prices with only the one generic to compete with.

The fifth, and final, consideration is whether the settlement was unjustifiably large pursuant to an analysis determining the rationale behind the settlement.¹⁷⁰ The brand drug manufacturer can attempt to preserve its monopoly in forms other than

¹⁶⁶ Actavis, 2236.

¹⁶⁷ Payment After Actavis, 42.; Antitrust Analysis of Reverse Payment After Actavis: Three Questions and Proposed Answers, at 16, *available at* http://www.ftc.gov/system/files/documents/public_statements/591131/141010actavisspeech.pdf; Federal Trade Commission, Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2010: A Report by the Bureau of Competition, at 1 (May 2011) *available at* <http://www.ftc.gov/os/2011/05/1105mmaagreements.pdf>.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* at 2237.

physical monetary payments. The no-authorized-generic agreement is highly lucrative to both the brand name drug and the generic. Empirically, this does not involve a physical passing of money from the brand manufacturer to the generic manufacturer, but rather the benefits are realized through the money earned in the market by forcing the consumers to succumb to their high prices. Like Chief Justice Roberts stated, there is no real difference between physically getting money and earning that money as a product of the agreement.¹⁷¹ Value is still exchanged whether it's a monetary agreement or whether money is made from the performance of the agreement. The courts should keep pace with drug manufacturers and be more practical by including non-monetary settlements in their antitrust scrutiny.

VII. Conclusion

The Supreme Court in *Actavis* determined that the rule-of-reason analysis was the proper test for reverse payment settlements; however, they left it open to the lower courts to decide how to apply it. The Supreme Court did not define payment and instead, the Court obscures the actual definition of payment by applying it only to monetary payments. The Supreme Court formulated five considerations, within the rule of reason, for courts to utilize when evaluating antitrust claims. These five considerations can and should be applied to non-monetary payments as well. Although courts have implied that the Supreme Court's intention is for the analysis to only apply to monetary settlements, the lower courts should not be this narrow and should not refrain from applying it to non-monetary settlements.

¹⁷¹ Loestrin, *30.

No-authorized-generic provisions are agreements between the brand name drug manufacturer and the generic drug manufacturer. The brand name drug manufacturer promises not to keep their generic version of the drug out of the market so the generic drug manufacturer can enjoy their 180 days of exclusivity from the Hatch-Waxman Act with true exclusivity. These provisions can be converted into a monetary estimate by using methods such as, looking at the difference of pricing and sales between the 180 days with authorized generic in the market with the generic and without the authorized generic in the market with the generic. Therefore, these provisions should not escape antitrust scrutiny merely because there was no physical passing of money. These provisions still represent an exchange of value. If the generic drug manufacturer received significant consideration as an incentive or benefit to stay out of the market, and the plaintiff offers this as a factual basis, then the courts should proceed to the antitrust scrutiny regardless of the actual form of consideration. The non-monetary settlements are still anti-competitive, and the deterrence of agreements that suppress or prevent competition is the main goal of the Sherman Act. Consequently, the *Actavis* opinion and the rule of reason should be applied to both monetary and non-monetary reverse payment settlements.